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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,438	11/13/2001	Bernard A. Hausen	032405-059 US	7508

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EXAMINER	
ROBERTS, PAUL A	

ART UNIT	PAPER NUMBER
3731	17

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,438	HAUSEN ET AL.	
	Examiner	Art Unit	
	Paul A Roberts	3731	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspondence addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-47* is/are pending in the application.

4a) Of the above claim(s) *9 and 19-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-18 and 45-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3 9 12*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 5-8, 11-18, & 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paolitto et al. "Paolitto" US 2003/0010346 in view of Sterman et al. US 5735290 in view of Donlon US 6110187 in view of Wolf et al. US 6066144. Paolitto discloses a method of performing a closed-chest, beating-heart, coronary anastomosis. A sub-xyphoid point of entry is made. Paolitto uses sutures to anastomose the vessel to the graft and does not disclose performing an anastomosis on both the proximal and distal anastomosis sites. In figure 3, Sterman shows a closed-chest approach to coronary bypass surgery. In col. 14, lines 17-30, Sterman discloses that any conventional technique may be applied to connect the graft to the vessel. He specifically lists stapling. Figures 9-13 show the graft being attached. Additionally, Sterman discloses the step of tensioning the target vessel by a grasping member 102, in figure 8.Tool 96 would go through one of the chest openings. Figure 8 shows the step of opening the target vessel. The grasper of Sterman splits to release the vessel. A grasper as shown in figure 3, inherently opens the blades (splits) to release the object the blades are holding. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Sterman stapling technique and method with the Paolitto anastomosis system because stapling provides a facilitated mechanism to anastomose a vessel. Paolitto is silent about completing both a distal and a proximal anastomosis between the graft vessel and the two vessels, but this method is well known in the art. Performing an anastomosis to join two vessels and a graft to

reroute blood would require performing an anastomosis of the proximal and distal vessel. Donlon specifically discloses this method (see attached paragraph) to perform an anastomosis during beating-heart surgery. At the time of the invention it would have been obvious to one having ordinary skill in the art to use the Donlon method in combination with the combined Paolitto method of performing closed-chest surgery because performing an anastomosis between the graft and the distal and proximal vessels would provide an effective method to anastomose the vessels together. Neither Sterman, Paolitto, nor Donlon explains in detail the method of stapling. The Wolf endoluminal stapler is disclosed to be used for anastomosis. Col 10, 25-60 details the method of use of the device which includes stapling a graft vessel to the target vessel, inserting an anvil through the wall of the target vessel into the lumen of the target vessel, and moving the anvil against the side of the target vessel. The stapler of Wolf deploys the anastomosis device (the staple) to the target vessel. The Wolf device is especially designed to minimize trauma associated with manipulating blood vessels (col. 4, 5-15). At the time of the invention it would have been obvious to one of ordinary skill in the art to use the Wolf stapler with the combined Paolitto method because stapling is a known anastomosis technique and the Wolf stapler provides a method and apparatus to minimize manipulation of the blood vessels. The Wolf device has an anvil and is intended to be used in an end-to-side anastomosis.

2. Regarding claim 11, the combined Paolitto device discloses the ports shown in figure 3 are called trocar sheaths (Sterman).

3. Regarding claims 12 and 13, the combined Paolitto device discloses in col. 13, lines 18-28 that the step of creating a hole in the pericardium is required to allow the instruments access to the innards of the heart (Sterman).

4. Regarding claim 14, a clamp is shown in figure 8 as item 102 (Sterman).

5. Regarding claim 15, the graft vessel, shown as element 101, is sliced in figure 8 (Sterman).

6. Regarding claim 16, the clamp tool shown in figure 8 is connected to the tool 32 in figure 3. The handle of the clamp assembly is considered the tool that is attached to the clamp (Sterman).

7. Regarding claim 17, the anastomosis site is viewed through a scope as described in col. 6 lines 54-60 (Sterman).

8. Regarding claim 18, the combined Paolitto reference discloses all of claim 1, but doesn't disclose the step of performing at least one additional proximal and distal anastomosis. The additional steps would be repeated for each bypass needed to be performed. The method of performing a double or triple bypass requires a repetition of said additional steps. At the time of the invention it would have been obvious to one having ordinary skill in the art to repeat the steps of attaching two vessels to a graft for patients requiring an additional bypass because it is well known in the art that multiple bypasses are performed when multiple blood vessel obstructions exist.

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined Paolitto device as applied to claim 1 and in further view of Berg et al. US 6475222. The combined Paolitto reference discloses all of claim 1, but does not disclose the necessary step of measuring the vein in the anastomosis site by using a tool that is inserted through the thoracic cavity. This step is necessary (but not disclosed by Sterman) because one could not simply guess the length of the graft to place into the body. The graft must span the distance of the anastomosis

site. Additionally, the step of measuring the length of the graft with a vein-measuring device is explicitly taught by Berg in col. 11, lines 20-23. At the time of the invention it would have been to one of ordinary skill in the art to use the vein measuring device of Berg to measure the length of the graft to be anastomosed in the combined Paolitto method because it is necessary to measure this distance to ensure the graft is long enough to span the gap between the vessels.

Response to Arguments

10. Pg. 11, paragraph 1 of the applicant's amendment of 12/19/03, the rejection has been modified to take into account the limitations in newly amended claim 1. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

11. Pg. 12, paragraph 2 of the applicant's amendment of 12/19/03, it is noted claim 1 does not require a grasper or blades currently. Their presence or absence is indeed irrelevant to claim 1. Thus the applicant's arguments about what those parts do or do not inherently perform are also irrelevant.

12. Pg. 12, paragraph 3, the applicant is denying that it is well-known in the art to finish ananastomosis bypass. It isn't clear, to the examiner, how else one would perform a bypass surgery if they did not connect the graft to the two different vessels. Arguendo, in anticipation of that argument, a combination with Dolan '187 (and proof of the fact that completing the anastomosis is indeed well-known in the art) was made in the previous Office action. Without

an argument against that combination, it is assumed the applicant acquiesces the rejection's proper construction.

13. Pg. 12, paragraph 4, claim 1, is not currently allowable, but if it is amended to be allowable, all other claims are still generic to claim 1.

14. Pg. 13, paragraph 1, the applicant should note col. 1 lines 10-15, where Wolf explicitly refutes the applicant's argument that the Wolf device is intended solely for side-to-side anastomosis. The Wolf device is both structured to and capable of performing a side-to-end anastomosis.

15. Pg. 13, paragraph 2, claims 14-17 are currently, and were intended to be, rejected under the combination of Paolitto, Sterman, Dolan, and Wolf. While this intention appears clear from the record, the applicant nonetheless misconstrued the omission (of claims 14-17 into the rejection in paragraph 5 of the previous Office action) to mean the Sterman reference alone renders obvious the limitations of claims 14-17. This of course is not true. Currently, the typographical error has been fixed in this action, and the claims 14-17 are rejected under the entire combination above.

16. Pg. 13, paragraph 2, (2nd argument), there is nothing 'unfairly characterized' in the rejection. A handle is within the scope of a distal anastomotic tool. A tool is a device to perform work. An anastomosis tool is a device to perform anastomosis work. The handle of figure 3 clearly meets this limitation.

17. Pg 13, paragraph 3, the applicant's point is persuasive, and the examiner has modified the rejection to include the limitation that the graft must be at least as long as the length of space between the vessels. However, this point does not obviate the rejection, because one would still

need to measure the length of the graft space to determine the minimum length of the graft that would need to be used.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts
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02/09/04

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

Depending on the preference of the surgeon, the proximal anastomosis, which joins the graft vessel to the aorta, can be performed before or after the distal anastomosis, which joins the graft vessel to one or more of the coronary arteries. The distal anastomosis is generally performed while the patient's heart is stopped, whereas the proximal anastomosis may be performed with the heart stopped or while the heart is still beating, according to the preferences of the surgeon. To stop the heart, a special endo-aortic clamping catheter, which is described in the aforementioned patent applications, is inserted into the ascending aorta via a percutaneous entry or a surgical cutdown into the femoral artery. An endo-aortic clamping balloon on the distal end of the catheter is inflated in the patient's ascending aorta to block blood flow in the patient's aorta downstream of the coronary arteries. Cardioplegic solution is immediately infused into the patient's coronary arteries through a lumen in the catheter to temporarily stop the patient's heart from beating. Alternatively, the proximal anastomosis can be performed while the heart is still beating by using a side-biting clamp or other device to isolate a portion of the aortic wall from the aortic blood circulation. With a portion of the aortic wall isolated from the systemic circulation by either of these methods, the proximal anastomosis can be performed using any of the devices and methods previously described herein.